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SEAL FOR A CONNECTOR OF A MOVEABLE CATHETER SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. Provisional Patent Application No. 60/453,846, filed March 10, 2003, the content of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a seal for a catheter system of a medical device. The present invention is particularly useful for sealing a catheter connection and allowing the catheter to move relative to the connector. It is to be understood that the terms "medical device" and "medical field", as used herein, include traditional medicine as well as alternative medicines including chiropractic, acupuncture, etc., as well as the veterinary field.

BACKGROUND OF THE INVENTION

[0003] In numerous applications of devices in the medical field, it may be necessary or desirable to create a fluid-tight seal between structural components of a catheter system. For many catheter-based devices, creating such as seal is manifestly critical to the safety and reliability of the devices. It is often important for medical devices to incorporate a mechanism to prevent liquid or gasses, including air, from contacting certain device elements, entering the body through the catheter, seeping in, such as where suction pressure may be diluted, or leaking out of the device, such as where suction pressure may be lost.

[0004] An intracorporeal device that uses a catheter system may be employed for therapeutic and/or diagnostic procedures. For example, a device to remove obstructions, including partial or total occlusions or other lesions of various types, from a target site in the body, e.g. a blood vessel, is well established treatment modality in interventional cardiology. Numerous methods and devices that employ catheters have been conceived and developed. For example, catheter systems are widely used in atherectomy or thrombectomy devices for

the treatment of arterial occlusions and may be inserted within a patient at various sites on or in the body. Atherosclerosis is a condition arising from the deposition of fat-like matter, i.e. plaque, on the walls of blood vessels. As a result of accumulated obstructions, blood flow becomes restricted or blocked, creating health risks, including coronary artery disease, angina and heart attacks.

[0005] In general, catheters are tubular structures that may are used as a passageway into a body. Although the term, "catheter", as used herein, is intended to include one or a combination of many types of conventional catheters that are widely known in the medical field. One type of catheter, for example, is commonly referred to as a "guiding catheter" and has a lumen and a distal orifice through which other devices such as guidewires, other catheters, and the like may be guided and manipulated. Another type of catheter, referred to as an "operating catheter" herein, has a functional portion, i.e. "operating head", generally at the distal tip, that is useful for gathering information and/or performing a diagnostic or therapeutic function. Typically, the operating head is translated or manipulated through the guiding catheter and to a target site in the body, where the operating head may be activated. The operating catheter system may include various layers, lumens, connectors, bearings, and/or other devices that communicate with the operating head. For example, the catheter system may include one or more drive shaft(s), guidewire(s), catheter(s), protective sheath(s), optical fiber(s), cable(s), wire(s), etc. In some systems, a catheter is employed to effectively isolate the rotating elements of the device, such as a drive shaft, from direct contact with any healthy body matter, e.g. tissue. Connection between various catheters and/or components is often required.

[0006] A standard adapter, such as a Y-adapter, and/or a Touhy Borst valve, consists of an open straight channel which accepts a guide wire and catheter, and an angled secondary channel that attaches to a manifold for pressure monitoring, contrast injection, flushing, etc. Such connectors of catheter components and associated joints in catheter systems typically incorporate proximally a hand tightened valve, often called a hemostatic valve, with a rubber O-ring or similar ring. It is difficult to tighten a hemostatic valve to prevent leaks and still provide for low friction movement of the catheter or device the valve seals around. Frictional heating by an O-ring may also be destructive to the seal. Moreover, an O-ring is typically molded and imperfect in structure.

[0007] Some Y-adapters use a self closing valve (such as Co-Pilot™ Y-adapter available by Guidant Corporation, located in Indianapolis, IN) in conjuction with a rotating hemostatic valve. However, this valve also uses certain materials, such as silicon rubber or the like, that have relatively high coefficient of friction and require spring forces to close such that motion of a catheter through the valve is slightly impeded. Thus, standard connectors do not efficiently permit movement of the enclosed catheter.

[0008] It is further important that such joints between components are sealed in particular intracorporeal devices that force aspiration through the catheter to urge materials through the catheter. For atherectomy or thrombectomy procedures, it has been found that steps to collect dislodged particulates from accumulating in the body are critical. For example, findings have shown that stent deployment to treat interventional treatment for acute coronary syndrome (ACS) is often associated with plaque embolization in patients with ACS. See Circulation 2003; 107:2320-5. This heart damage increases the risk of long-term adverse clinical outcomes. In another example, kidneys are known to be very susceptible to blockage if embolisms occur in a renal artery during renal interventions. In the case of treatment of deep vein thrombosis, complications also occur if a clot breaks off and travels in the bloodstream to the lungs.

[0009] Some current devices employ filter systems to catch loosened debris. However, filter systems may allow small particles to pass and may be poorly positioned against a vessel wall. Other current devices use aspiration as an effective means to remove via suction embolic particulates that have been extracted from the body and provide embolic protection. However, it is important for the aspiration to be consistently maintained and at high rate. A tight seal must be provided between catheters and/or catheter components so that aspiration is not lost through cracks in the joint between device components. Moreover, a seal must prevent air from getting into the aspiration area and competing with aspiration for space. Further, it is particularly important that the seal is maintained for applications that require obtaining accurate blood pressure readings with the use of the intracorporeal device.

[0010] Some catheter systems do not require movement of the catheter, such as balloon devices. For applications that require moving components, one particular connector is useful at the proximal end of the guide catheter to permit an operating catheter or guide wire to pass through this guide connector and extend into the guide catheter.

[0011] It is therefore desirable to provide a fluid-tight seal at junctions for various catheter system components that permits the catheter components to move with low friction for precision manipulation of the catheter system. In particular, a connector that maintains a fluid-tight seal while permitting the smooth sliding of components, such as lateral translation, is needed for a catheter system. The seal should be adaptable to be useful in by a variety of connector types. The present invention fulfills these needs and provides further related advantages.

SUMMARY OF THE INVENTION

[0012] A slip seal adapter is provided for insertion within a connector of catheter components, to seal the catheter and permit the catheter to move in a lateral and/or rotational direction. The adapter includes a rigid tube that is sized for insertion within the connector and a thermally shrinkable wrap extending from the tube at an extension section of the wrap. A lumen in the adapter receives a catheter that passes through a bore in the catheter. The extension section of the shrinkable wrap sealably surrounds a portion of the catheter. The shrinkable wrap comprises a lubricious material that permits slip of the catheter and yet maintains the seal.

[0013] Although the adapter may be inserted in the connector in various ways, in one embodiment the distal portion of the tube is insertable within the connector and the extension section extends from the distal portion of the tube. A tightening segment of the connector, e.g. a Touhy Borst valve, securely clenches the tube. At times, the connector is a Y adapter that comprises at least one side port for passage of material into or from the catheter. For example, the connector may be provided to connect an operating catheter system with a guiding catheter.

[0014] A portion of the shrinkable wrap covers the tube and is shrinkable to a first diameter that is at least substantially the diameter of the tube and the extension section is shrinkable to a diameter that is at least substantially the diameter of the catheter. The shrinkable wrap may comprise PTFE, Teflon®, FEP or PFA.

[0015] The adapter and connector is useful in various intracorporeal medical devices. One such device comprises an operating head coupled to a distal end of a catheter system. The catheter system encloses a drive shaft which couples to a drive system to be rotated. The catheter system passes through a bore in the connector and a lumen in the adapter. The extension section of the shrinkable wrap allows the catheter to be manipulated into and away from the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The present invention is illustrated by way of example in the figures of the accompanying drawings and the figures are not intended for limitation, which figures are not intended to limit the present invention, and in which:

[0017] Figure 1 is a schematic diagram of an external view of a slip seal adapter implemented in an intracorporeal medical device, according to one embodiment of the present invention;

[0018] Figures 2A and 2B are enlarged schematic diagrams of the slip seal adapter, according to one embodiment of the present invention, wherein Figure 2A is an angled external view of one slip seal adapter and Figure 2B is an internal view of one slip seal adapter;

[0019] Figures 3A and 3B are enlarged schematic diagrams of external views of a catheter connector system having a slip seal adapter and a connector at a catheter junction, wherein Figure 3A shows components exploded from the junction, and Figure 3B shows a Y adapter with a Touhy Borst valve and a slip-seal adapter according to one embodiment of the present invention;

[0020] Figure 4 is an enlarged schematic diagram of internal views of a catheter connector system including a slip seal adapter inserted into a connector at a catheter junction; and

[0021] Figure 5 is a perspective diagram illustrating one intracorporeal medical device that may incorporate the present slip seal adapter.

DETAILED DESCRIPTION OF THE INVENTION

[0022] A slip seal adapter is provided for insertion within a connector of catheter components, in which at least one of the catheter components may be moveable relative to the connector. The system comprising the adapter inserted within the connector is referred to herein as "connector system." The adapter includes a rigid tube and a thermally shrinkable wrap extending from the tube. A lumen runs through the adapter to permit the catheter to pass through the connector and through the adapter lumen, whereby the shrinkable wrap sealably surrounds a portion of the catheter. The shrinkable wrap comprises a lubricious material that permits the enclosed catheter to move in a lateral and/or rotational direction and yet maintains the close contact with the catheter.

[0023] As shown by example in Figure 1, one particular medical device 2 that may incorporate a slip seal adapter 6 of the present invention is an intracorporeal medical device having a catheter system extending from a drive system to inside of a patient's body. The medical device includes components that are inserted and navigated within the patient's body while an operator uses the medical device, and these components are generally continuous with and/or in communication with components for placement external to the patient.

[0024] As used herein to describe various components of the medical device including the sealing assembly affixed to the medical device, the term "proximal" refers to a direction or area away from the end of the device to be first inserted into a body, and "distal" refers to the direction or area toward such insertion portion.

[0025] In this particular example of a connector system, the extracorporeal components of the medical device 2 essentially comprise a guiding catheter 8 that is inserted into the body 12 at an insertion point 14. The guiding catheter terminates at its proximal end at the connector 4. The slip seal adapter 6 is inserted within the connector 4 at the connector's proximal end. A catheter 10 that surrounds a drive shaft passes through the guiding catheter and through the connector 4 to a drive system 16. The drive system rotates the drive shaft and may be any means of manually, such as by hand, or automatically rotating the drive shaft, such as a motor, e.g. a high-speed electric motor or a pneumatic-powered motor.

[0026] The drive shaft may be any elongated tube that is rotatable. Oftentimes, the drive shaft is a flexible, hollow, helical, torque-transmitting shaft. A multi-filar stainless steel coil drive shaft having a bi- tri- or quad-filar construction is often employed. A coil drive shaft

having an inner diameter of from about .015 to .025 inch and an outer diameter of from about .025 to .035 inch is typical for atherectomy applications. In some applications, the drive shaft may be rotated at high speeds of about 500 rpm to 200,000 rpm may be used, more typically about 10,000 to 100,000 rpm and more often about 40,000 rpm, or more.

[0027] The connector having a slip seal adapter may be positioned at various locations along the length of the catheter system that is external to the body. Along the length of the catheter system there may be one or more connectors that may link various layers and components of the catheter system. Typically, the connector system, i.e. the connector and inserted adapter, is positioned at the proximal end of the guiding catheter, where it is desirable to hold the guiding catheter stationary while sliding the catheter to and from the body.

[0028] Figures 2A and 2B show views of one embodiment of the slip seal adapter. The external view of the adapter 50 as depicted by Figure 2A generally includes a rigid tube 52, a thermally shrinkable wrap 54 and a lumen 58 extending through the tube and wrap. The slip seal adapter may be any convenient length that fits within and may be secured by the connector, such as about 1.0 inch to 2.0 inches in length.

[0029] One embodiment further includes an optional handle 56 to make for easier handling of the adapter. The handle may be provided in any convenient location that which assists insertion of the adapter into the connector. Typically the handle is positioned at the proximal end of the adapter and includes the lumen.

[0030] A portion of the adapter is an insertion segment 60 capable of fitting within a connector and includes at least a portion of the tube and the shrinkable wrap. As shown in Figure 2B, a portion of the tube 52 may be positioned inside of the handle 56. In one embodiment, the insertion segment 60 includes the entire length of the tube 52 that is external to the handle 56. However, the insertion segment may also extend from the wrap to any shorter portion of the tube external to the handle.

[0031] The tube comprises a rigid material, such as steel. The tube may be any convenient length and diameter that fits within the connector, such as 1.0 to 2.0 inches long and less than .110 of the outer diameter and more typically between about .110 and .080 inch. The wall of the tube is often about .002 to .006 inch. It is usually desirable to provide

sufficient clearance between the catheter and the tube so that there is very little or no friction at the hemostatic seal.

[0032] The thermally shrinkable wrap 54 attaches to the tube and also includes an extension section 62 that extends from the tube to wrap around a portion of the catheter. The extension section is capable of adhering to the catheter to create a seal and permitting the catheter to slip within the wrap. The length of the extension segment is sufficient to permit seal and slip of the underlying catheter. In one embodiment, the extension section of the wrap is about .10 inch in length.

[0033] The wrap is attached to the tube by shrinking the wrap over the exterior surface of the tube. The wrap may cover the entire length of the tube or any portion thereof, such that the wrap is securely attached to the tube. In one embodiment, the wrap covers the portion of the tube that is clamped by the connector, such that the connector clamps onto the wrap as well as the tube. In this manner, there is no interruption of the outer adapter surface between the seal of the catheter by the extension section and the hemostatic seal of the connector to the adapter.

[0034] At least the extension section of the wrap, and typically the entire wrap comprises Teflon® (by e.i. DuPont De Nemours and Company Corporation located in Wilmington, DE), or other similar lubricious material comprising the slip seal adapter permits smooth slipping of the catheter within the extension section, yet the adapter provides an effective seal against the catheter. The types of heat shrink material may also include, but not limited to, polytetrafluorothylene (PFTE) polymer, FEP, PFA, etc. In many applications it is desirable to use high thermal resistant material that melts at higher temperatures, such as PTFE, which melts at about 650 degrees F, whereas FEP melts at between 400 to 500 deg. F. The sheath is very thin, such as .001 to .002 inch.

[0035] The lumen 58 allows the catheter to pass through the adapter 50. The lumen is larger than the diameter of the catheter and typically slightly larger. For instance, where a .075 inch catheter is used within the adapter, the lumen may be between about .090 to .100 inch in diameter.

[0036] As shown in Figure 3A, the slip seal adapter 100 is easily insertable within the connector 102. Typically, the adapter is be fitted at one or both ends of the connector. In one embodiment, the adapter 100 is inserted at one end of the connector 102, such as the

proximal end, and the terminal end of an outer catheter 104, such as the terminal proximal end of a guiding catheter, is inserted into the opposite end of the connector, such as the distal end. The insertion portion is inserted into an opening 118 at the connector, such as the proximal end of the connector. The diameter of the insertion section measures smaller than the diameter of the opening 118 such that the tube fits snuggly within the connector. As illustrated in Figure 3B, in one embodiment, the handle 106 of the slip seal adapter 100 may remain external to the connector 102 after insertion.

[0037] Although the figures show essentially one way that the slip seal adapter associates with the connector, other configurations of the adapter with the connector are possible and intended to be within the scope of the present invention, whereby the connector clamps around the tube to form a seal. For example, in another embodiment, the adapter tube is inserted into the proximal opening of the connector and the extension section of the shrinkable wrap covers the catheter externally from the connector. In this particular insertion configuration, the extension section of the wrap is positioned proximal to the tube of the adapter, rather than distal to the tube as shown in the example of Figure 3B.

[0038] The connector 102 may be any suitable connecting element that seals a catheter from fluid leakage, such as at the terminal end of an outer catheter or at a joint between two ends of two catheters. The connector includes a tightening section 112, such as a snap-seal. The present slip seal adapter is easily employed with several conventional connectors known in the art. Some typical connectors include a Y-adapter, Touhy Borst valve, etc.

[0039] The connector 102, such as a Y-adapter for example, may also have one or more side port 110 from a main tube 116. The side port is for infusion of substances, such as drugs and/or injecting contrast to view the target site for the catheter in making certain that the catheter is its proper position. The port 110 of the connector may also be used for fluid extraction, such as taking a blood sample to measure the rate of blood clots and. In one embodiment, the connector 102 is a Y-adapter having may be a tightening segment 112 that is a Touhy Borst rotating hemostatic valve.

[0040] Figure 4A and the enlarged view of Detail F shown in Figure 4B show the connector 202 clamped around the slip seal adapter 200 to form a hemostatic seal at a junction located at the proximal end of a guiding catheter 208. The extension section 204 of the shrinkable wrap partially covers the tube 206 and partially covers the catheter 210 to

create a smooth and slippable seal between the catheter 210 and the bore 212 of the connector the without allowing fluid leakage. Whereas the shrinkable wrap portion that surrounds the tube is shrunk to a first diameter, the extension section of the slip seal adapter is shrunk to a second diameter that is substantially or equal to the diameter of the catheter that is to be inserted into the connector system. By the wrap shrinking to at least substantially the diameter of the catheter, a precise fluid tight seal is formed, which creates little translational friction. The extension section snuggly covers a portion of the catheter. The slip seal adapter of the present invention when used with a Touhy Borst valve may withstand very high pressure, such as at least 40 psi.

[0041] The catheter 210 may further contains a drive shaft 220 and/or guide wire. At times, the catheter may include a wired support element 222, such as a contiguous spiral coil, braid and/or weave of wire or ribbon. The catheter 210 passes from the distal end 224 of the connector and through the bore 212 of the connector to the proximal end 226 of the slip seal adapter 200. The proximal end of the slip seal adapter may comprise a handle 214 that remains external to the connector.

[0042] The slip seal adapter allows the catheter to laterally translate toward and away from the patient. During the removal operation, it is often necessary to direct the operating head that is attached to the distal end of the catheter, back and forth (i.e. laterally translate). The operator may create this movement by pushing and/or pulling at the proximal end of the catheter. The slip seal adapter create very little or no friction during such lateral translation of the catheter against the adapter in the connector.

[0043] A wide variety of operating heads coupled to the distal end of the catheter for diagnostic or therapeutic surgical procedures within a body cavity is well known to those skilled in the art. For example, types of operating head may include a cutting head having one or more cutting surfaces, such as a rotary cutter with one or more blades or abrasives; a heating element for performing thermal ablation; electrodes for performing electrosurgical cutting and cauterization; abrasive elements for performing mechanical ablation; fluid jet stream tip; optical waveguides for performing laser ablation; ultrasonic transducers for imaging and ablation; angioscopic imaging devices; and the like. A more detailed description an exemplary operating head and intracorporeal medical device in which the connector

system of the present invention may be used is provided in U.S. Patent No. 6,565,588 B1, filed on November 28, 2000, the contents of which is incorporated herein by reference.

[0044] One example of a medical device that may employ the connector system is useful in diagnosis and includes a probing operating head, such as an ultrasonic transducer. The diagnostic device may be useful in several medical fields. For example, in cardiology the operating head may be used to inspect the inside of the heart to identify abnormal structures or functions. The device may also be useful in measuring blood flow through the heart and other vessels. In urology, the device may be used to see kidney stones, measure blood flow through the kidney, detecting prostate cancer, etc.

[0045] Figure 5 depicts one exemplary embodiment of the intracorporeal medical device 300 that may employ the connector system of the present invention. A catheter system 302 that comprises an operating head at a distal end and a power source, e.g. drive system, at a proximal end, is provided. The catheter system may be inserted within a connector system of the present invention to join with other device components. In one embodiment, the slip seal adapter is strung over the length of the catheter and is available for insertion into any connector.

[0046] A tubing system 304 extends from a hand held unit 306, e.g. tracking pod, to a receiving container 308 that collects fluid and/or particles flowing from the catheter system. The tracking pod may house the drive system, one or more connectors, system controls, etc. An infusate source 310 may also be provided to release fluid into the catheter system, when desired. At the proximal location of the medical device, a console unit 312 may further be provided to receive control information from an operator and/or present operation information to the operator. The console unit 312 may also provide a power source for the motor and an aspiration source. One or more pump(s) 314 may also be provided to provide aspiration for drawing materials from the catheter system and to receiving container 308. In one embodiment, console unit 312 and pump 314 are provided as a re-usable unit. In another embodiment, the hand held tracking pod 306 and control buttons may also be provided as a reusable unit. The catheter system often includes multiple layers of components such as a drive shaft, one or more sheaths, optional guidewire, etc.

[0047] The present invention has been described above in varied detail by reference to particular embodiments and figures. However, these specifics should not be construed as

limitations on the scope of the invention, but merely as illustrations of some of the present embodiments. It is to be further understood that other modifications or substitutions may be made to the described connector and slip seal adapter. For example the connector and adapter may be useful to create a moveable seal for numerous different types of catheters. Furthermore, the slip seal adapter is intended to be functional with a variety of connectors that may clamp around a rigid member, e.g. tube, of the adapter. The specific examples provided are not intended to limit the types of catheters and connectors used with the adapter that are known or will be determined in the future.